



وزارة الصحة
Ministry of Health
مستشفى القنفذة العام

Policy & Procedure (P&P)

Policy Title :

Malaria Test for Donors

Department	Index No.	Scope
Laboratory & Blood Bank	LAB-073	All Blood Bank and Lab Staff
Issue Date	Revision NO	Effective Date
1432/10/24	3	1440/07/23
Review Due Date	Related Standard NO.	Page Number#
1442/07/23	CBAHI (LB.51)	3

01. Policy:

Whole blood or blood components will not be used for transfusion unless results of malaria parasite test (by rapid test or by direct smear film) is negative.

02. Definition :

Pf: Plasmodium Falciparum

03. Purpose :

To provide safe and parasite free blood and blood products.

04. Procedure :

4.1. Sample: EDTA whole blood.

4.2. Reagent and Supply:

Giemsa stain (ready to use).

Incubator.

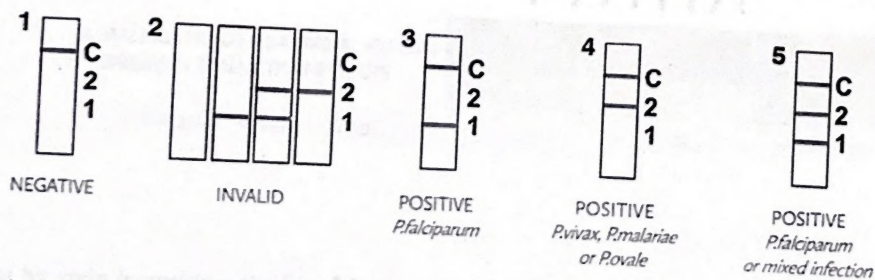
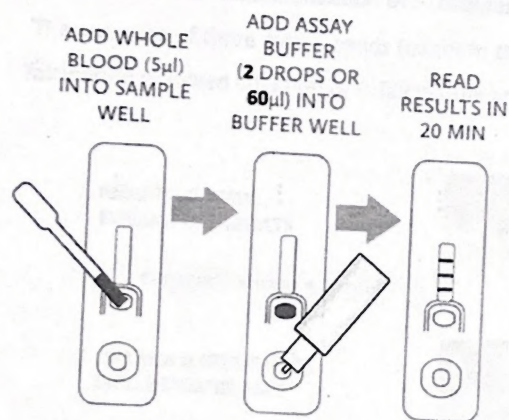
Slide for film preparation.

Light microscope.

Care start TM Malaria Pf/PAN Ag combo RDT rapid test

4.3. Rapid test procedure using Care start TM Malaria Pf/PAN Ag combo RDT kit

- Collect the blood sample (5 μ l) using a pipette provided or micropipette.
- Add 5 μ l of whole blood into the 'S' well.
- Add 60 μ l assay buffer solution (3 drops for vial type or 2 drops for bottle type) into the "A" well.
- Start a timer.
- Read result in 20 minutes.



Results Interpretation of the test

1. Negative reaction

The presence of only one band in the Control Area within the result window indicates a negative result.

2. Invalid

The test is invalid if the line in the Control Area does not appear. If this occurs, the test should be repeated using a new strip.

3. Positive reaction

- *P. falciparum* The presence of three colour bands (three bands in the Control, "2" and "1" areas) or two bands (one band in the Control Area and another band in the "1" area) indicates a positive result for *P. falciparum*.

4. **Positive reaction P. vivax, P. malariae, or P. ovale.**

The presence of two colour bands (one band in the Control Area and another band in the "2" area) indicates a positive result for P. vivax, P. malariae, or P. ovale. The pLDH present in the sample reacts with the pan anti-pLDH conjugate and move through the test strip where the pLDH is captured by pan specific anti-pLDH.

5. **Positive reaction - mixed infection of P. falciparum and other species**

The presence of three colour bands (bands in the Control, "2" and "1" areas) indicates a positive result for P. falciparum or mixed infection of P. falciparum and other species.

1. MALARIA P. VIVAX EVALUATION RESULTS	PV - POSITIVE CONFIRMED SPECIMEN		SENSITIVITY
	POSITIVE	NEGATIVE	
CARESTART™ MALARIA AG RAPID	96	4	96/100 X 100% = 96%

2. MALARIA P. FALCIPARUM EVALUATION RESULTS	PF - POSITIVE CONFIRMED SPECIMEN		SENSITIVITY
	POSITIVE	NEGATIVE	
CARESTART™ MALARIA AG RAPID	98	2	98/100 X 100% = 98%

3. MALARIA NEGATIVE NORMAL HUMAN SPECIMEN EVALUATION RESULTS	RANDOM NORMAL HUMAN SPECIMEN		SPECIFICITY
	POSITIVE	NEGATIVE	
CARESTART™ MALARIA AG RAPID	5	195	195/200 X 100% = 97.5%

If the result by strip is positive, the blood bank technician will prepare a thick and a thin smear and give to the blood bank consultant to read on microscope and give the final result

4.4. **Malaria test by thick and thin smears**

4.4.1. A drop of blood ,3-5 in diameter is put into the center of glass slide and spread to cover an oval area of approximately 10-15 mm in diameter.

04.1.1. Thoroughly dry the smear horizontally in an incubator at 37degree Celsius for one hour.

04.2. Staining method:

- 04.2.1. Do not fix the dry film, but place it gently on coplin jar containing Giemsa stain (freshly prepared 1:10 Giemsa:water) for 30 min.
- 04.2.2. Rinse briefly with tap water and drain dry.
- 04.3. Examine the film by microscope under 100 high power.

Note:

The species involved in transfusion transmitted malaria are *P. falciparum* (35%), *P. malaria* (27%), *P. vivax* (27%), and *P. ovale* (5%).

Asymptomatic carriers are generally the source of transfusion-transmitted malaria, although their parasite density is very low.

Asymptomatic infections rarely persist more than 3 years, but asymptomatic *P. falciparum* and *P. vivax* infections may persist for 5 years, *P. ovale* for 7 years, and *P. malaria* can remain transmissible for the life time of the asymptomatic individual.

There are no practical serologic tests to detect transmissible malaria in asymptomatic donors. Malaria transmission is prevented by deferral of prospective donors with increased risk of infectivity, based on their medical and travel history.

The AABB requires that prospective donors who have had a diagnosis of malaria, or who have traveled or lived in a malaria-endemic area and have had unexplained symptoms suggestive of malaria, be deferred for 3 years after becoming asymptomatic.

Individuals who have lived for at least 5 consecutive years in areas in which malaria is considered endemic by the CDC Malarial Branch shall be deferred for 3 years after departure from that area.

Individuals who have traveled to an area where malaria is endemic shall be deferred for 12 months after departing that area. These deferral periods apply irrespective of the receipt of antimalarial prophylaxis.

05. Responsibilities :

- 05.1. All Blood Bank and Laboratory Staff of Al-Qunfudah General Hospital.

06. Equipment & Forms

06.1. Malaria Test Form

07. Attachment :

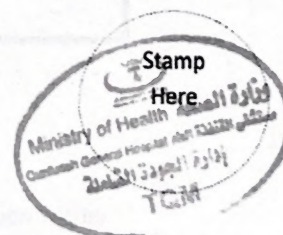
N/A

08. Reference

- 08.1. The unified practical procedure manual for blood banks in the Arab countries.
08.2. The Technical Manual of the American Association of Blood Banks.

Preparation , Reviewing & Approval Box

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BLOOD GROUPING AND MALARIA FOR DONORS

2020-7-22

SERIAL NUMBER	MALARIA	Sickling test

Performed by

Approved by